

METHODS OF TREATING CHRONIC OBSTRUCTIVE PULMONARY DISEASE

FIELD OF THE INVENTION

[0001] The invention relates to methods and devices to allow expired air able to pass out of the lung tissue to facilitate both the exchange of oxygen ultimately into the blood and/or to decompress hyper-inflated lungs. The invention also directed to methods and devices to altering gaseous flow within a lung to improve the expiration cycle of an individual, particularly individuals having Chronic Obstructive Pulmonary Disease (COPD).

BACKGROUND OF THE INVENTION

[0002] The term “Chronic Obstructive Pulmonary Disease” (COPD) is generally used to describe the disorders of emphysema and chronic bronchitis. Previously, COPD was also known as Chronic Obstructive Lung Disease (COLD), Chronic Airflow Obstruction (CAO), or Chronic Airflow Limitation (CAL). Some also consider certain types of asthma to fall under the definition of COPD. Emphysema is characterized by an enlargement of air spaces inside the lung. Hence, Emphysema is an anatomic definition and it can only be presumed in a living patient. Chronic bronchitis is characterized by excessive mucus production in the bronchial tree. Chronic bronchitis is a clinical definition and denotes those individuals who meet criteria defining the disease. It is not uncommon for an individual to suffer from both disorders.

[0003] In 1995, the American Lung Association (ALA) estimated that between 15-16 million Americans suffered from COPD. The ALA estimated that COPD was the fourth-ranking cause of death in the U.S. The ALA estimates that the

rates of emphysema is 7.6 per thousand population, and the rate for chronic bronchitis is 55.7 per thousand population.

[0004] Those inflicted with COPD face disabilities due to the limited pulmonary functions. Usually, individuals afflicted by COPD also face loss in muscle strength and an inability to perform common daily activities. Often, those patients desiring treatment for COPD seek a physician at a point where the disease is advanced. Since the damage to the lungs is irreversible, there is little hope of recovery. Most times, the physician cannot reverse the effects of the disease but can only offer treatment and advice to halt the progression of the disease.

[0005] To understand the detrimental effects of COPD, the workings of the lungs requires a cursory discussion. The primary function of the lungs is to permit the exchange of two gasses by removing carbon dioxide from venous blood and replacing it with oxygen. Thus, to facilitate this exchange, the lungs provide a blood gas interface. The oxygen and carbon dioxide move between the gas (air) and blood by diffusion. This diffusion is possible since the blood is delivered to one side of the blood-gas interface via small blood vessels (capillaries). The capillaries are wrapped around numerous air sacs called alveoli which function as the blood-gas interface. A typical human lung contains about 300 million alveoli.

[0006] The air is brought to the other side of this blood-gas interface by a natural respiratory airway, hereafter referred to as a natural airway or airway, consisting of branching tubes which become narrower, shorter, and more numerous as they penetrate deeper into the lung. Specifically, the airway begins with the trachea which branches into the left and right bronchi which divide into lobar, then segmental bronchi. Ultimately, the branching continues down to the terminal bronchioles which lead to the alveoli. Plates of cartilage may be found as part of the walls throughout most of the airway from the trachea to the bronchi. The cartilage plates become less prevalent as the airways branch. Eventually, in the last

generations of the bronchi, the cartilage plates are found only at the branching points. The bronchi and bronchioles may be distinguished as the bronchi lie proximal to the last plate of cartilage found along the airway, while the bronchiole lies distal to the last plate of cartilage. The bronchioles are the smallest airways that do not contain alveoli. The function of the bronchi and bronchioles is to provide conducting airways that lead inspired air to the gas-blood interface. However, these conducting airways do not take part in gas exchange because they do not contain alveoli. Rather, the gas exchange takes place in the alveoli which are found in the distal most end of the airways.

[0007] The mechanics of breathing include the lungs, the rib cage, the diaphragm and abdominal wall. During inspiration, inspiratory muscles contract increasing the volume of the chest cavity. As a result of the expansion of the chest cavity, the pleural pressure, the pressure within the chest cavity, becomes sub-atmospheric with respect to the pressure at the airway openings. Consequently, air flows into the lungs causing the lungs to expand. During unforced expiration, the expiratory muscles relax and the lungs begin to recoil and reduce in size. The lungs recoil because they contain elastic fibers that allow for expansion, as the lungs inflate, and relaxation, as the lungs deflate, with each breath. This characteristic is called elastic recoil. The recoil of the lungs causes alveolar pressure to exceed the pressure at airway openings causing air to flow out of the lungs and deflate the lungs. If the lungs' ability to recoil is damaged, the lungs cannot contract and reduce in size from their inflated state. As a result, the lungs cannot evacuate all of the inspired air.

[0008] Emphysema is characterized by irreversible damage to the alveolar walls. The air spaces distal to the terminal bronchiole become enlarged with destruction of their walls which deteriorate due to a bio-chemical breakdown. As discussed above, the lung is elastic, primarily due to elastic fibers and tissues called elastin found in the airways and air sacs. If these fibers and tissues become weak the

elastic recoil ability of the lungs decreases. The loss of elastic recoil contributes to more air to entering the air sacs than can exit preventing the lungs from reducing in size from their inflated state. Also, the bio-chemical breakdown of the walls of the alveolar walls causes a loss of radial support for airways which results in a narrowing of the airways on expiration.

[0009] Chronic bronchitis is characterized by excessive mucus production in the bronchial tree. Usually there is a general increase in bulk (hypertrophy) of the large bronchi and chronic inflammatory changes in the small airways. Excessive amounts of mucus are found in the airways and semisolid plugs of this mucus may occlude some small bronchi. Also, the small airways are usually narrowed and show inflammatory changes.

[0010] In COPD, a reduction in airflow arises as a result of 1) partial airway occlusion by excess secretions, 2) airway narrowing secondary to smooth muscle contraction, bronchial wall edema and inflation of the airways, and 3) reduction in both lung elasticity and tethering forces exerted on the airways which maintain patency of the lumen. As a result of the COPD, the airways close prematurely at an abnormally high lung volume. As mentioned above, in an emphysematous lung there is a decrease of lung parenchyma as there are larger and fewer air sacs. Thus, there is a decrease in the amount of parenchymal tissue which radially supports the airways. This loss of radial traction allows the airway to collapse more easily. As lung recoil decreases and airway closure occur at higher lung volumes, the residual volume of gas in the lung increases. Consequently, this increased residual gas volume interferes with the ability of the lung to draw in additional gas during inspiration. As a result, a person with advanced COPD can only take short shallow breaths.

[0011] One aspect of an emphysematous lung is that the flow of air between neighboring air sacs, known as collateral ventilation, is much more prevalent as compared to a normal lung. Yet, while the resistance to collateral ventilation may be

decreased in an emphysematous lung the decreased resistance does not assist the patient in breathing due to the inability of the gasses to enter and exit the lungs as a whole.

[0012] Currently, although there is no cure for COPD, treatment includes bronchodilator drugs, and lung reduction surgery. The bronchodilator drugs relax and widen the air passages thereby reducing the residual volume and increasing gas flow permitting more oxygen to enter the lungs. Yet, bronchodilator drugs are only effective for a short period of time and require repeated application. Moreover, the bronchodilator drugs are only effective in a certain percentage of the population of those diagnosed with COPD. In some cases, patients suffering from COPD are given supplemental oxygen to assist in breathing. Unfortunately, aside from the impracticalities of needing to maintain and transport a source of oxygen for everyday activities, the oxygen is only partially functional and does not eliminate the effects of the COPD. Moreover, patients requiring a supplemental source of oxygen are usually never able to return to functioning without the oxygen.

[0013] Lung volume reduction surgery is a procedure which removes portions of the lung that are over-inflated. The improvement to the patient occurs as a portion of the lung that remains has relatively better elastic recoil which allows for reduced airway obstruction. The reduced lung volume also improves the efficiency of the respiratory muscles. However, lung reduction surgery is an extremely traumatic procedure which involves opening the chest and thoracic cavity to remove a portion of the lung. As such, the procedure involves an extended recovery period. Hence, the long term benefits of this surgery are still being evaluated. In any case, it is thought that lung reduction surgery is sought in those cases of emphysema where only a portion of the lung is emphysematous as opposed to the case where the entire lung is emphysematous. In cases where the lung is only partially emphysematous, removal of a portion of emphysematous lung increases the cavity area in which the

non-diseased parenchyma may expand and contract. If the entire lung were emphysematous, the parenchyma is less elastic and cannot expand to take advantage of an increased area within the lung cavity.

[0014] Both bronchodilator drugs and lung reduction surgery fail to capitalize on the increased collateral ventilation taking place in the diseased lung. There remains a need for a medical procedure that can alleviate some of the problems caused by COPD. There is also a need for a medical procedure that alleviates some of the problems caused by COPD irrespective of whether a portion of the lung, or the entire lung is emphysematous. The production and maintenance of collateral openings through an airway wall which allows expired air to pass directly out of the lung tissue responsible for gas exchange. These collateral openings ultimately decompress hyper inflated lungs and/or facilitate an exchange of oxygen into the blood.

SUMMARY OF THE INVENTION

[0015] This invention relates to devices and methods for altering gaseous flow in a diseased lung. In particular, the inventive method includes the act of improving gaseous flow within a diseased lung by the step of altering the gaseous flow within the lung. A variation of the inventive method includes the act of selecting a site for collateral ventilation of the diseased lung and creating at least one collateral channel at the site. The term “channel” is intended to include an opening, cut, slit, tear, puncture, or any other conceivable artificially created opening. A further aspect of the invention is to locate a site within a portion of a natural airway of the respiratory system of the patient having the diseased lung. The portion of the natural airway selected for the creation of the collateral channels may be, for example, the bronchi, the upper lobe, the middle lobe, the lower lobe, segmental bronchi and the bronchioles.

[0016] A variation of the invention includes selecting a site for creating a collateral channel by visually examining areas of collateral ventilation. One variation includes visually examining the lung with a fiber optic line. Another example includes the use of non-invasive imaging such as x-ray, ultrasound, Doppler, acoustic, MRI, PET computed tomography (CT) scans or other imaging. The invention further includes methods and devices for determining the degree of collateral ventilation by forcing gas through an airway and into air sacs, reducing pressure in the airway, and determining the reduction in diameter of the airway resulting from the reduction in pressure. The invention further includes methods and devices for determining the degree of collateral ventilation by forcing a volume of gas within the lung near to the airway and measuring pressure, flow, or the return volume of gas within the airway. The invention also includes methods and devices for occluding a section the airway and determining the degree of collateral ventilation between the occluded section of the airway and the air sacs.

[0017] An important, but not necessarily critical, portion of the invention is the step of avoiding blood vessels or determining the location of blood vessels to avoid them. It is typically important to avoid intrapulmonary blood vessels during the creation of the collateral channels to prevent those vessels from rupturing. Thus, it is preferable to avoid intrapulmonary or bronchial blood vessels during the creation of the collateral channels. Such avoidance may be accomplished, for example by the use of non-invasive imaging such as radiography, computed tomography (CT) imaging, ultrasound imaging, Doppler imaging, acoustical detection of blood vessels, pulse oxymetry technology, or thermal detection or locating. The avoidance may also be accomplished using Doppler effect, for example transmission of a signal which travels through tissue and other bodily fluids and is reflected by changes in density that exist between different body tissue/fluids. If the signal is reflected from tissue/fluid that is moving relative to the sensor, then the reflected signal is phase

shifted from the original signal thereby allowing for detection. The invention includes devices having at least one sensor for the above described imaging methods. In variations of the invention having multiple sensors, the sensors may be arranged in a linear pattern or in an array pattern. Also, the invention may have a mark to serve as a reference point while the device is remotely viewed.

[0018] The invention may include adding an agent to the lungs for improving the imaging. For example, a gas may be inserted into the lungs to provide contrast to identify hyperinflation of the lungs during an x-ray or other non-invasive imaging. For example, ^{133}Xe (Xenon 133) may be used as the agent. Also, a contrast agent may help in identifying blood vessels during CT scans. Another example includes inserting a fluid in the lungs to couple an ultrasound sensor to the wall of an airway.

[0019] Another variation of the act of looking for blood vessels includes insertion of a probe into a wall of the natural airway for the detection of a blood vessel. Such a probe may, for example, detect the presence of a blood vessel upon encountering blood such as when the probe is inserted into a vessel. The probe may also use ultrasonic detection to determine the location of a vessel. For example, ultrasound may be used to determine changes in composition of the tissue beyond the airway wall for determination of the location of a vessel. A probe may, for example, use low frequency radio energy to induce heat at a point and determine the presence of a vessel by measuring a change in temperature due to the conduction of heat by the blood flowing within the vessel. Another variation is that the probe could detect changes in impedance given a pre-arranged discharge of current through the bloodstream. It is also contemplated that the probe is used, for example, purposely to find the blood vessel, so that an alternative site may be selected at a safe distance from the vessel.

[0020] Another variation of the invention is via the delamination of the blood vessel and the wall of an airway. This delamination may occur in many ways. For

instance, the airway may be expanded until the vessel separates from the wall of the airway. Or, a vacuum may be applied within the interior of the airway using, for example, two occlusive balloons or the like to isolate a portion of the airway and apply a vacuum. The vacuum between the balloons constricts the diameter of the airway by collapsing the walls of the airway until the exterior walls separate from any blood vessel.

[0021] The invention may also include providing a remotely detectable signal to indicate the presence or absence of any blood vessels at the target site. The invention also includes methods and devices for marking a desired site for the creation of a collateral channel.

[0022] The invention also includes the act of creating one or more collateral channels within the respiratory system of the individual. The collateral channels may have a cross sectional area anywhere between 0.196 mm^2 to 254 mm^2 . Any subset of narrower ranges is also contemplated. The collateral channels may also extend anywhere from immediately beyond the epithelial layer of the natural airway to 10 cm or more beyond the epithelial layer. The channel or channels should be created such that the total area of the channel(s) created is sufficient to adequately decompress a hyperinflated lung. The channel may be, for example, in the shape of a hole, slit, skive, or cut flap. The channel may be formed by the removal of any portion of the airway wall; e.g., a circumferential or arc-shaped ring of material may be removed to form the channel. Such an excised periphery may be for example, perpendicular or at angled with respect to the axis of the airway.

[0023] Another variation of the invention involves creation of a collateral channel by creating an incision in a natural airway and using a blunt member to push the vessel away from the path of a collateral channel. Another variation of forming the collateral channel is, for example, by use of a mechanical process such as dilation, cutting, piercing, or bursting. For example, a balloon may be used to expand an

incision made in the natural airway or the natural airway itself until a collateral channel is opened. Or, a mechanical cutter or piercing tool could be used to open and create the collateral channel. Another variation for creating a collateral channel includes making an incision in the natural airway and placing the wall of the airway in tension, then advancing a blunt instrument into the incision.

[0024] Also, it is anticipated that along with any method of creating a collateral channel any loose material or waste generated by the creation of the collateral channel is optionally removed from the airway.

[0025] Another variation for creating the collateral channel is the creation of the airway using electric energy, for example radio frequency. Or, for example, ultrasonic energy, a laser, microwave energy, chemicals, or cryo-ablative energy may be used to form a collateral channel as well. A feature of these methods often includes creation of a hemostasis in the event that any blood vessel is punctured. For example, use of RF energy provides a hemostasis given a puncture of a vessel by using heat to seal the vessel. Similarly, an ultrasonic scalpel also provides an area of hemostasis in case the vessel is punctured. It is understood that any combination of different methods may be used for forming a single or multiple collateral channels. A variation of the invention includes a limiter for limiting the depth of a collateral channel.

[0026] A variation of the inventive device includes a device that detects motion within tissue using Doppler measurements. The device may include a flexible member having a transducer assembly that is adapted to generate a source signal and receive a reflected signal. The inventive device may also comprise a hole-making assembly that is adapted to making collateral channels within tissue. The transducer assembly may include an acoustic lens which enables the transmission and detection of a signal over a tip of the device. The hole-making assembly may be an RF device

and use portions of the tip of the device as RF electrodes, or the hole-making assembly may use ultrasound energy to make the hole.

[0027] Another variation of the invention includes the act of inserting an implant or conduit within a collateral channel to maintain the patency of the channel over time during the expiration cycle of the lung. A conduit could, for example, have distal and proximal ends with a wall defining a lumen extending between the ends. The conduit could have, for example, a porous wall permitting the exchange of gasses through the wall. The conduit may, for example, be comprised of a material such as elastomers, polymers, metals, metal alloys, shape memory alloys, shape memory polymers, or any combination thereof. A variation of the invention includes an expandable conduit, either one that is self-expanding, or one that expands in diameter in relation to any applied radial, or axial force. For example, the conduit may be expanded into an opening of the natural airway upon the inflation of a balloon. A variation of the conduit may include the use of flanges or anchors to facilitate placement of the device within an airway. Another variation of the conduit includes placing a one-way valve within the conduit. Another variation includes using a self cleaning mechanism within the conduit to clear accumulating debris.

[0028] The inventive conduit may be, for example, removable or permanent. Also, another variation of the device includes a means for inserting the conduit within a collateral channel. The conduit may be constructed to allow for passage of gasses through its wall, for example, the conduit may have a wall consisting of a braid. A variation of the conduit may be located through an opening in a wall of an airway and engage both an inside and outside of the wall. Another variation of the conduit includes a distal end having a porous member and a proximal end having a grommet member which engages an opening in a wall of the natural airway. Yet another variation of the implant, for example, comprises an expandable conduit-like apparatus which could bridge an opening within a wall of a natural airway. Another variation

includes the conduit-like apparatus having a cutting portion exterior to the device wherein expansion of the device pierces the wall of the natural airway and creates a collateral channel.

[0029] An aspect of the invention is that conduits of varying cross-sectional areas may be placed in various sections of the lung to optimize the effect of the collateral channels.

[0030] Another variation of the invention includes the application of a cyanoacrylate, fibrin or other bio-compatible adhesive to maintain the patency of a collateral channel. The adhesive may be used with or without the conduit described above. For example, the adhesive may be deposited within the collateral channel to maintain patency of the channel or to create a cast implant of the channel. The inventive act further includes the act of delivering medications such as steroids which have been shown to inhibit the healing process, bronchodilators, or other such drugs which aid in breathing, fighting infection, or recovery from the procedure. The steroids inhibit inflammation and then promote the stabilization of the created channel.

[0031] Another variation of the inventive process includes promoting the flow of gasses through under-utilized parenchymal inter-conduits, or bypassing restricted airways. It is also contemplated that the gaseous flow may be altered by, for example, making separate inspiratory and expiratory paths. Also, relieving pressure on the external wall of a natural airway may be accomplished to assist the natural airway by maintaining patency during the expiration cycle of the lung. Yet another variation includes creating collateral channels parallel to existing airflow paths, or the existing airflow paths may be increased in cross-sectional area.

[0032] The invention further includes a device for altering gaseous flow in a diseased lung comprising a locator for locating a site for collateral ventilation of the lung, and optionally, a creating means for opening at least one collateral channel at

the site. It is contemplated that the device includes a means for locating a blood vessel as described above. Also, as stated above, the device may use a mechanical, electrical, laser, ultrasonic, microwave, or chemical process for creating a collateral channel. Another variation of the device includes a means for coagulating blood upon the entry of the device into a blood vessel. Yet another variation of the device includes the means for locating and the means for creating are the same. The device may further include a means for simultaneously creating a plurality of collateral channels.

[0033] Another variation of the implant includes conduits constructed from materials that oppose the constriction of the natural airway over time during the expiration cycle of the lung. Yet another variation of the implant includes a device which expands as the pressure in the lung decreases during the expiration cycle.

[0034] The invention further includes a modified respiratory airway having an artificially created channel allowing gaseous communication between an exterior of the airway and an interior of the airway.

[0035] The invention may include an endoscope or a bronchoscope configured to select sites and create collateral channels at those sites. An endoscope or a bronchoscope may also be configured to deploy conduits within the collateral channels. Another variation of the invention includes sizing the device to fit within the working channel of a bronchoscope.

[0036] The invention also includes methods for evaluating an individual having a diseased lung for a procedure to create collateral channels within an airway of the individual. The invention further includes the method of determining the effectiveness of the procedure.

[0037] The invention further includes the act teaching any of the methods described above.

[0038] The invention further includes the method of sterilizing any of the devices or kits described above.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] Figure 1A-1C illustrates various states of the natural airways and the blood-gas interface.

[0040] Figures 1D-1G illustrate devices and methods for determining the degree of collateral ventilation within a lung.

[0041] Figure 2A illustrates a natural airway with a collateral channel in relation to a blood vessel.

[0042] Figures 2B-2K illustrate methods of avoiding blood vessel prior to the creation of a collateral channel.

[0043] Figures 2B-2E illustrate various methods for delaminating an airway from a blood vessel.

[0044] Figure 2F illustrates the use of a probe to determine a site for creating a collateral channel.

[0045] Figures 2G-2K illustrate the use of sensors to determine a site for creating a collateral channel.

[0046] Figures 3A-3I illustrate methods of and devices for creating a collateral opening within a natural airway.

[0047] Figures 3J-3K illustrate a method of folding epithelial tissue through a collateral channel.

[0048] Figure 4 illustrates a device and method for simultaneously creating numerous collateral channels or deployment of numerous probes.

[0049] Figures 5A-5W illustrate various configuration of implantable conduits.

- [0050] Figures 6A-6D illustrate devices for detecting blood vessels within tissue.
- [0051] Figures 6E-6O illustrates various devices for detecting blood vessels within tissue where the devices also include hole-making assemblies.
- [0052] Figures 6P-6V illustrate various electrode configurations for the hole-making assemblies of the device.
- [0053] Figures 7A-7B illustrate devices and methods for creating a collateral channel with a device having a hole-making assembly and also preserving the tissue surrounding the collateral channel.
- [0054] Figures 7C-7D illustrate additional electrode configurations for use with a device of the present invention where the structure of the electrodes limits the possible depth of a collateral channel formed by the electrode.
- [0055] Figures 8A-8U illustrate variations of conduits of the present invention.
- [0056] Figures 9A-9I illustrate variations of methods and devices for deployment of conduits of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

- [0057] Prior to considering the invention, simplified illustrations of various states of a natural airway and a blood gas interface found at a distal end of those airways are provided in Figures 1A-1C. Figure 1A shows a natural airway **100** which eventually branches to a blood gas interface **102**. Figure 1B illustrates an airway **100** and blood gas interface **102** in an individual having COPD. The obstructions **104** impair the passage of gas between the airways **100** and the interface **102**. Figure 1C illustrates a portion of an emphysematous lung where the blood gas interface **102** expands due to the loss of the interface walls **106** which have deteriorated due to a bio-chemical breakdown of the walls **106**. Also depicted is a constriction **108** of the

airway **100**. It is generally understood that there is usually a combination of the phenomena depicted in figures 1A-1C. More usually, the states of the lung depicted in figures 1B and 1C are often found in the same lung.

[0058] The following illustrations are examples of the invention described herein. It is contemplated that combinations of aspects of specific embodiments or combinations of the specific embodiments themselves are within the scope of this disclosure.

[0059] As will be explained in greater detail below, central to this invention in all of its aspects is the production and maintenance of collateral openings or channels through the airway wall so that expired air is able to pass directly out of the lung tissue and into the airways to ultimately facilitate exchange of oxygen into the blood and/or decompress hyper inflated lungs. The term 'lung tissue' is intended to include the tissue involved with gas exchange, including but not limited to, gas exchange membranes, alveolar walls, parenchyma and/or other such tissue. To accomplish the exchange of oxygen, the collateral channels allow fluid communication between an airway and lung tissue. Therefore, gaseous flow is improved within the lung by altering or redirecting the gaseous flow within the lung, or entirely within the lung. Figure 1D illustrate a schematic of a lung **118** to demonstrate a principle of the invention described herein. As shown, a collateral channel **112** places lung tissue **116** in fluid communication with airways **100** allowing expired air to directly pass out of the airways **100**. As shown, constricted airways **108** may ordinarily prevent air from exiting the lung tissue **116**. In the example illustrated in Figure 1D, conduits **200** may be placed in the collateral channels **112** to assist in maintaining the patency of the collateral channels **112**. Therefore, it is not necessary to pierce the pleura to improve gaseous flow within the lungs. While the invention is not limited to the number of collateral channels which may be created, it

is preferable that 1 or 2 channels are placed per lobe of the lung. For example, the preferred number of channels is 2-12 channels per individual patient.

[0060] Accordingly, since the invention is used to improve the function of the lungs, a variation of the inventive device may include an endoscope or a bronchoscope configured to locate a site for creating a collateral channel and create the collateral channel. Another variation includes sizing the inventive device to fit within a working channel of an endoscope or a bronchoscope. For the sake of brevity, hereafter, any reference made to an endoscope includes the term bronchoscope.

[0061] The invention includes assessing the degree of the collateral ventilation taking place in an area of a lung to select a site for creation of a collateral channel. The invention may include locating a site for creation of a collateral channel by visually examining an airway for dynamic collapse. One method of visual examination includes the use of a fiber optic line or camera which may be advanced into the lungs and through the airways. Other variations of visually examining the lung to determine the location of a site for the creation of the collateral channel using non-invasive imaging, including but not limited to radiography, computer tomography, ultrasound, Doppler, and acoustic imaging. Such imaging methods may also be used to determine the amount of collateral channels to be created.

[0062] Also contemplated in the invention is the addition of various agents to assist during imaging of the airways or lungs. One example includes the use of a non-harmful gas, such as Xenon, to enhance the visibility of hyperinflated portions of the lung during radiological imaging. Another example includes the use of inserting a fluid in the lungs to provide an improved sound transmission medium between the device and the tissue in variations of the invention using ultrasound, acoustic, or other imaging.

[0063] Another variation of the invention includes methods and devices for triggering a collapse of the airway to determine the degree of collateral ventilation in the lung. One example includes forcing a fluid, such as a gas, air, oxygen, etc., through the airway and into the air sacs. Next, to assess the patency of the airway, the pressure is reduced in the airway. One example of how pressure is reduced in the airway includes evacuating the air in a direction opposite to the air sacs. Constriction of the airway given a drop in pressure may be an indication of collateral ventilation of the lung in that region.

[0064] Figure 1E, illustrates a method and device **212** for causing collapse of the airway wall **100**. The device **212** includes a fluid delivery member **214** located at a distal end of the device **212**. The fluid delivery member **214** is configured to deliver a volume of fluid through the airway **100** and into an air sac (not shown). The device **212** may also comprise a probe **216** configured to collect data within the lung. The probe **216** may also simply consist of a channel that transmits signals outside of the lung. Moreover, the fluid delivery member **214** and the probe **216** may not be separate channels. Also, the device **212** may, but does not necessarily, have an occlusion member **218** designed to isolate a section of the airway **100** between the occlusion member **218** and the air sacs (not shown). The occlusion member **218**, which forms a seal against the airway **100** walls, may provide a partially closed system allowing a more effective search for collateral ventilation between the air sacs (not shown.) The device delivers a burst of fluid, through the fluid delivery member **214** and subsequently uses the probe **216** to measure characteristics such as pressure, flow, or return volume to determine the degree of collateral ventilation. The term fluid is intended to include, air or a gas, such as oxygen, etc. For example, if the air sacs are diseased (as shown in figure 1C), the forced fluid will escape/disperse through another air sac due to the collateral ventilation of the air sacs. As a result, the probe **216** may fail to record any increase in pressure, volume, flow, or any other

characteristic of the fluid at the site. Another variation of the invention includes using the fluid delivery member **214** to add or remove fluid distally to the occluded segment and using the probe **216** to monitor flow or pressure changes in the area. For example, if after adding/removing fluid the pressure in the occluded segment fails to build/drop, the assumption may be made that the gas is being collaterally vented through diseased air sacs.

[0065] Figure 1F illustrates another variation of the invention. In this example, the device **220** comprises a separated probe **216** and gas delivery member **214**. In this variation, the fluid delivery member **214** is configured to pass through a wall of the airway **100** so that fluid may be directly forced into, or pulled out of an air sac **102**.

[0066] Figure 1G illustrates yet another variation of the invention. In this variation, the device **222** may have at least one fluid exchange passageway **224**. The device **222** may force fluid into the airway **100** via the passageway **224**. Then, fluid can be pulled out via the passageway **224**, thus decreasing pressure distally to the device **222**. The decrease in pressure permits fluid to flow out of the airway **100** and away from the air sac (not shown). In this case, if the air sacs surrounding the airway **100** are diseased and collateral ventilation is taking place, then the airway **100** may collapse. A variation of the invention may include an expandable member **218**, such as a balloon, to create a seal against the airway **100** walls. Forming a seal may provide a partially closed system to search for collateral ventilation between air sacs (not shown.) As described above, observation of a collapsing airway **100** may indicate a desired site for creation of a collateral channel.

[0067] Figure 2A illustrates a blood vessel **110** on an outer wall of an airway **100**. In this figure, the collateral channel **112** created using this invention is located away from the vessel wall **110**. Such a positioning of the collateral channel **112** eliminates the risk of rupturing the vessel **110** during formation of the collateral

channel **112**. As mentioned above, the term channel is intended to include an opening, cut, slit, tear, puncture, or any other conceivable artificially created opening.

[0068] Of course, it is not the case that blood vessels are necessarily as conveniently located as is seen in Figure 2A. Consequently, it may be desirable to move the vessels or to avoid them. Figure 2B illustrates a first way of moving the nearby vessel. Figure 2B shows the inflation of the airway **100** using a balloon **204** provided on a delivery device **202**. As shown in figure 2C, upon deflation of the balloon **204**, the airway **100** and the vessel **110** become delaminated thereby moving the vessel from the region just outside the exterior of the airway. Subsequent creation of a collateral channel using the inventive procedures will be less likely to hit the vessel.

[0069] Figure 2D demonstrates another device **206** and method for delaminating an airway **100** from a vessel **110**. In this variation, the two balloons (**204** & **205**) occlude the airway **100**. As shown in figure 2E, upon application of a vacuum, the vessel **110** and the airway **100** delaminate as the airway **100** separates from the vessel **110**. It may be desirable to make a channel while the airway is contracted as shown in figure 2E.

[0070] Figure 2F illustrates the insertion of a probe **210** into a wall of the airway **100**. Although, the probe **210** is illustrated to be a singular probe, the delivery device **208** may be adapted to have multiple probes. As described above, the probe **210** may detect the presence of blood such as when the probe is inserted into a vessel. For example, the probe **210** could be configured to puncture a wall of the airway **100**, and detect the presence of blood. Optionally, the probe **210** could pull a vacuum to facilitate entry of blood into the probe **210**. The probe **210** may also use ultrasonic detection to determine the location of a vessel. For example, ultrasound may be used to determine changes in composition of the tissue beyond the airway wall for determination of the location of a vessel. A probe **210** may, for example, use low

frequency radio energy to induce heat at a point and determine the presence of a vessel by measuring a change in temperature due to the conduction away or removal of heat by the blood flowing within the vessel. Another variation is that the probe **210** could detect changes in impedance given a pre-arranged discharge of current through the bloodstream. If a probe **210** detects blood during its travel outside the airway, the user could select another spot for a collateral channel.

[0071] Another variation of the invention includes methods and devices for determining whether a blood vessel is in proximity to a potential site. Making this determination prior to creating the channel is advantageous as the risk of puncturing a blood vessel is minimized. As mentioned above, non-invasive imaging may be used to locate blood vessels or to confirm the absence of a vessel at a site. Figure 2G illustrates an example of this variation of the device **226** having a single sensor **228**. The device may be, but is not necessarily, steerable and rotatable such that the sensor **228** can be placed in contact with any portion of the airway **100** wall. In non-steerable variations, the device may be located to a site by the use of an endoscope. The device **226** may also be stiff so that the sensor **228** may be placed in firm contact with a wall of the airway **100**. It is important that the device does not 'wander' causing the creation of a collateral channel at a distance from the area originally searched. Such an occurrence may compromise a blood vessel (e.g., puncture, rupture, or otherwise open the blood vessel) even though the step of detecting the location indicated the absence of a blood vessel. In those cases, a stiffer wall provides added benefits.

[0072] Another variation of the invention includes inserting a fluid into the airway to provide a medium for the sensor **228** couple to the wall of the airway **100** to detect blood vessels. In those cases where fluid is not inserted, the device may use mucus found within the airway to directly couple the sensor **228** to the wall of the airway **100**.

[0073] Figure 2H illustrates another variation of the inventive device **230** having a plurality of sensors **228** arranged in an array pattern. Although not shown, the array could extend around the circumference of the device **230**. Figure 2I illustrates yet another variation of the inventive device. In this example, the device **232** comprises a plurality of sensors **228** arranged in a linear pattern. Although not shown, the pattern may also wind helically or in other patterns around the perimeter of the device **232**.

[0074] Figure 2J illustrates another variation of the invention. In this example, the device **234** comprises a sensor **228** encapsulated by an expandable member **236** e.g., a balloon. The expandable member **236** may be filled with a fluid or other substance that couples the sensor **228** to an outer surface of the expandable member **236**. The sensor **228** may be rotatable within the expandable member **236**, or the entire device **234** may be rotatable within the airway **100**. Another variation of the device **234** includes a mark **238** which provides a reference for orientation of the device **234** in the airway **100**. The mark **238** is preferably remotely detectable and may be positioned on the expandable member **236**.

[0075] Another variation of the invention includes a means for marking the site. This variation of the device allows marking of the site after it is located. Accordingly, once marked, a previously selected site can be located without the need to re-examine the surrounding area for collateral ventilation, or the presence or absence of a blood vessel. The marking may be accomplished by the deposit of a remotely detectable marker, dye, or ink. Or, the marking may comprise making a physical mark on the surface of the airway to designate the site. Preferably, the mark is detectable by such imaging methods as radiography, computer tomography (CT) imaging, ultrasound imaging, doppler imaging, acoustical detection, or thermal detection or locating. Also, the mark may be detectable by direct visualization such as the case when a fiber optic cable is used. Figure 2K illustrates an example of the

device **240** having a sensor **228** to locate a site and a marking lumen **242** which may deposit an ink, dye, or other marker (not shown) on the site once located.

[0076] Although not illustrated, the invention may include a user interface which provides feedback once an acceptable site is located. For example, once a site is located a visual or audible signal or image is transmitted to the user interface to alert the user of the location of a potential site. The signal could be triggered once a blood vessel is located so that the site is selected in another location. In another example, the signal may trigger so long as a blood vessel is not located.

[0077] Figures 3A-3I depict various ways of providing openings in the airway wall which may be used as collateral air passageways.

[0078] Figure 3A illustrates an airway **100** having a piercing member **300** and a dilation member **302**. In this example, the piercing member **300** makes an incision (not shown) in the airway **100** wall. Next, the piercing member **300** is advanced into the wall so that a dilation member **300** can expand the incision to thereby provide a collateral channel. In this example, the dilation member **300** is depicted as a balloon. One variation of the invention includes filling a balloon with a heated fluid as the balloon dilates the tissue to form the collateral channel. Use of a heated balloon allows the transfer of heat to the collateral channel for modifying the healing response. However, it is also contemplated that the dilation member may be an expanding wedge (not shown) or other similar device.

[0079] Figure 3B shows a cutting device **304** and an airway **100** having an opening **306** cut from a wall. In this example, a flap **308** is cut from the wall and is attached to an outside or an inside wall of the airway **100**. As will be mentioned below, the flap may be glued, using for instance, fibrin-based or cyano-acrylate-based glues or stapled to that wall.

[0080] Figure 3C illustrates a cutter **304** making an incision **310** in a wall of the airway **100**. Figure 3D illustrates one example of placing the walls of the airway

100 in tension and inserting a blunt instrument **314** into the incision. In this example, the delivery device **312** is flexible and may be shaped to the contour of an airway **100** to provide support for the blunt instrument **314** so that the instrument **314** can advance into the incision.. The delivery device **312** is also used to deliver a blunt instrument **314** which expands the original incision. The blunt instrument **314** may have a hooked configuration as needed.

[0081] Figure 3E shows the use of a balloon **320** to dilate a previously formed collateral channel in the airway wall **100**. This procedure may be used variously with other mechanical, chemical, cryo-energy or RF based penetration systems to expand the size of that previously-formed opening.

[0082] Figure 3F illustrates a variation of the device **322** having an RF electrode **324**. This variation of the invention uses RF energy to create a collateral channel. The device **322** may be mono-polar or bi-polar. The RF energy throughout this invention is similar to that of a typical RF cutting probe operating between the 300KHz-600KHz range.

[0083] Figure 3G-3I illustrates additional variations of devices of the present invention used to create collateral channels. The devices may use RF energy, either monopolar or bipolar, or the devices may use light, infrared heat, or any of the other methods describe herein. In the variation of figure 3G, the device **328** has an electrode **324** located on a side of the device. This variation of the device **328** automatically limits the depth of the collateral channel as the body of the device **328** remains against an airway **100** wall while the electrode **324** creates a channel.

[0084] Figure 3H and 3I illustrates another variation of a device **330** of the present invention having an electrode **324** located on a front face of the device. Figure 3I illustrates a perspective view of the device **330** with an electrode on the front face **324**. The device **330** may either have an electrode **324** disposed on a front surface of the device **330** or the device may comprise a conductive material with an

insulating layer **332** covering the device **330** and leaving an electrode surface **324** exposed. In the variations illustrated in figures 3G-3I, the size of the electrode may be selected based upon the size of the desired collateral channel.

[0085] The device of the present invention may also be configured to limit the depth of the collateral channel. In one example, the invention may include a shoulder or stop **326** to limit the depth of the collateral channel. Another example includes graduated index markings on a proximal end of the device or on the distal end so long as they are remotely detectable. Also contemplated is the use of RF impedance measuring. In this example, the use of RF impedance may be used to determine when the device leaves the wall of the airway and enters the air sac or less dense lung tissue.

[0086] The invention also includes creating a collateral channel by making a single or a series of incisions in an airway wall then folding back the cut tissue through the collateral channel. This procedure allows the surface epithelium which was previously on the inside of the airway wall to cover the walls of the newly formed collateral channel. As discussed herein, promoting growth of the epithelium over the walls of the collateral channel provides a beneficial healing response. The incision may be created by the use of heat or a mechanical surface. For example, Figure 3J illustrates a section of an airway **100** having several incisions **356** forming a number of sections **358** of airway wall tissue the airway **100**. Figure 3K illustrates the sections or flaps **358** of the airway wall folded through the collateral channel **112**. Any number of incisions **358** may be made to form any number of sections **358** of airway wall tissue as desired. For example, a plus-shaped incision would result in four sections of tissue that may be folded through a channel. The sections **358** may be affixed with a suture material, an adhesive, or the sections **358** may simply be inserted into surrounding tissue to remain folded through the collateral channel **112**.

[0087] Another variation of the device includes safety features such as probes to determine the presence of blood. If a probe indicates that a blood vessel is contacted or penetrated, a signal is sent which prevents the channel making device from causing further harm to the vessel. Such a feature minimizes the risk of inadvertently puncturing a blood vessel within the lungs.

[0088] Although the examples depict mechanically forming a collateral opening, the invention is not limited to such. Alternative methods of forming the opening are contemplated in the use of RF energy, bi-polar, or single pole electrosurgical cutters, ultrasonic energy, laser, microwave, cryo-energy or chemicals.

[0089] The present invention includes the use of a device which is able to detect the presence or absence of a blood vessel by placing a front portion of the device in contact with tissue. One variation of the invention includes the use of Doppler ultrasound to detect the presence of blood vessels within tissue. It is known that sound waves at ultrasonic frequencies travel through tissue and reflect off of objects where density gradients exist. In which case the reflected signal and the transmitted signal will have the same frequency. Alternatively, in the case where the signal is reflected from the blood cells moving through a blood vessel, the reflected signal will have a shift in frequency from the transmitted signal. This shift is known as a Doppler shift. Furthermore, the frequency of the signals may be changed from ultrasonic to a frequency that is detectable within the range of human hearing.

[0090] The ultrasound Doppler operates at any frequency in the ultrasound range but preferably between 2Mhz-30Mhz. It is generally known that higher frequencies provide better the resolution while lower frequencies offer better penetration of tissue. In the present invention, because location of blood vessels does not require actual imaging, there may be a balance obtained between the need for

resolution and for penetration of tissue. Accordingly, an intermediate frequency may be used (e.g., around 8 Mhz).

[0091] Figure 6A illustrates a variation of a device **600** adapted to determine the presence of blood vessels as previously mentioned. The device **600** includes a flexible elongate member **604** having a transducer assembly **606**, at least a portion of which is located adjacent to a distal end of the elongate member **604**. Although the elongate member **604** is illustrated as having a lumen, the elongate member **604** may also be selected to be solid, or the elongate member **604** may have a support member (not shown) such as a braid to increase the strength and/or maneuverability of the device. The transducer assembly **606** is adapted to generate a source signal and receive a reflected signal. It may use a single transducer or multiple transducers. For example, at least a first transducer may be used to generate a signal and at least a second transducer may be used to receive the signal.

[0092] The transducer or transducers use may comprise a piezo-ceramic crystal. In the current invention, a single-crystal piezo (SCP) is preferred, but the invention does not exclude the use of other types of ferroelectric material such as poly-crystalline ceramic piezos, polymer piezos, or polymer composites. The substrate, typically made from piezoelectric single crystals (SCP) or ceramics such as PZT, PLZT, PMN, PMN-PT. Also, the crystal may be a multi layer composite of a ceramic piezoelectric material. Piezoelectric polymers such as PVDF may also be used. The transducer or transducers used may be ceramic pieces coated with a conductive coating, such as gold. Other conductive coatings include sputtered metal, metals, or alloys, such as a member of the Platinum Group of the Periodic Table (Ru, Rh, Pd, Re, Os, Ir, and Pt) or gold. Titanium (Ti) is also especially suitable. For example, the transducer may be further coated with a biocompatible layer such as Parylene or Parylene C. . The transducer is then bonded on the lens. A coupling such as a biocompatible epoxy may be used to bond the transducer to the lens. The

transducer assembly 606 communicates with an analyzing device 602 adapted to recognize the reflected signal or measure the Doppler shift between the signals. As mentioned above, the source signal may be reflected by changes in density between tissue. In such a case, the reflected signal will have the same frequency as the transmitted signal. When the source signal is reflected from blood moving within the vessel, the reflected signal has a different frequency than that of the source signal. This Doppler effect permits determination of the presence or absence of a blood vessel within tissue. Although depicted as being external to the device 600, it is contemplated that the analyzing device 602 may alternatively be incorporated into the device 600. The transducer assembly of the invention is intended to include any transducer assembly that allows for the observation of Doppler effect, e.g., ultrasound, light, sound etc. The device 600 illustrated in figure 6A includes a transducer assembly 606 comprising an ultrasound transducer 608 and an acoustic lens 610 that is adapted to refract and disperse a source signal over an outer surface of the lens 610. The lens 610 is designed such that it interferes and redirects the signals in a desired direction. The lens 610 may be comprised of materials such as dimethyl pentene (plastic-TPX), aluminum, carbon aerogel, polycarbonate (e.g., lexan), polystyrene, etc. It also may be desirable to place an epoxy between the lens 610 and the transducer 608. Preferably, the epoxy is thin and applied without air gaps or pockets. Also, the density/hardness of the epoxy should provide for transmission of the signal while minimizing any effect or change to the source signal. The configuration of the transducer assembly 606 permits the lens 610 to disperse a signal over a substantial portion of the outer surface of the lens 610. The lens 610 also is adapted to refract a reflected signal towards the transducer 608. Accordingly, given the above described configuration, the device 600 of figure 6A will be able to detect vessels with any part of the lens 610 that contacts tissue (as illustrated by the line

612-612.) Although the lens 610 is illustrated as being hemispherical, as described below, the lens 610 may have other shapes as well.

[0093] Figure 6B illustrates another variation of the device 614 having a hemispherical shaped ultrasound transducer 618 affixed to an end of a flexible elongate member 616. The transducer 618 communicates with an analyzing device (not shown) to measure the Doppler effect to determine the location of a blood vessel.

[0094] Figure 6C illustrates another variation of the device 620 including a transducer assembly 622, at least a portion of which is located adjacent to a distal end of the elongate member 628. The transducer assembly 622 includes a flat ultrasound transducer 626, and a cone or wedge-like acoustic mirror 624. The mirror 624 is adapted to reflect the signal over an area 360° around the device. The angle α of the mirror may be varied to optimally direct the signal as needed.

[0095] Figure 6D illustrates a variation of a device 630 of the present invention further comprising a joint 632 to articulate an end of the device either to make sufficient contact with an area of tissue to be inspected for the presence of a blood vessel, or to navigate within the body to access the area to be inspected.

[0096] The variations of the invention described herein may also be adapted to use ultrasound energy, for example, high energy ultrasound, to produce openings in or marks on tissue. In such a case, the transducer assembly and acoustic lens also functions as a hole-making or site marking device. In this case, use of ultrasound in a low power operation permits the detection of a blood vessel and location of a site for a collateral channel. Using the same device and switching the operation of the device to a high power ultrasound permits the use of the ultrasound to create a collateral channel.

[0097] Figure 6E illustrates a variation of a device 632 comprising a transducer assembly 634 connected to a flexible elongate member 636. In this example, the transducer assembly 634 comprises a first transducer 641, a second

transducer 642, and an acoustic lens 640. As mentioned above, in variations using alternate transducers 641, 642, one transducer may transmit a signal while the other receives a signal. Also, both transducers 641, 642 may simultaneously transmit and receive signals. It is intended that any combination of using the transducers to send and receive signals is contemplated. The device 632 also includes a hole-making assembly 638 for creating a channel in tissue. Figure 6E illustrates the hole-making assembly 638 as an RF wire-like member. As illustrated, the device 632 is connected to an RF generator 644 as well as an analyzing device 646 which is adapted to measure the Doppler shift between the generated and reflected signals.

[0098] Figure 6F illustrates the device 632 of Figure 6E where the hole-making assembly 638 is retracted within the device 632, in this case within the elongated member 636.

[0099] Figure 6G illustrates another variation of a device 648 where a hole-making assembly 650 is exterior to a transducer assembly 606. The hole-making assembly 650 may be either an RF device or a mechanical device that simply cuts the tissue. For example, the hole making assembly 650 can be a hypotube placed over the transducer assembly 606. In this variation of the device 648, the transducer assembly 606 may be moveable within the hole-making assembly 650, or the hole-making assembly 650 may be moveable over the transducer assembly 606. In either case, the transducer assembly 606 may be advanced out of the hole-making assembly 650 to determine the presence of a blood vessel. If no blood vessel is found, the transducer assembly 606 may be withdrawn into the hole-making assembly 650 allowing the hole-making assembly 650 to create a channel in the tissue either by mechanically cutting the tissue, or by using RF energy to create the channel. Figure 6H illustrates a view taken along the line 6H in Figure 6G.

[00100] Figure 6I illustrates another version of a device 652 of the present invention wherein the device has a transducer assembly 654 with an opening 658

through which a hole-making assembly **656** may extend. Figure 6J illustrates the hole-making assembly **656** extended through the transducer assembly **654**. The hole-making assembly **656** may comprise RF electrodes or needle-like members which puncture the tissue to create the channels.

[00101] Figure 6K illustrates a variation of a device **666** of the present invention where a tip **660** of the device has a conductive portion allowing the tip to serve as both an acoustic lens and an RF electrode. In such a case, the tip **660** is connected to an RF generator **644** for creating channels within tissue and a transducer **662** is placed in communication with an analyzing device **646** that is adapted to measure the Doppler shift between generated and reflected signals. In this variation, the tip **660** is separated from the transducer **662**, but both the tip **660** and transducer **662** are in acoustic communication through the use of a separation medium **664**. The separation medium **664** transmits signals between the tip **660** and the transducer **662**. The spacing of the transducer **662** from the tip **660** serves to prevent heat or RF energy from damaging the transducer **662**. It is intended that the spacing between the transducer **662** and tip **662** shown in the figures is for illustration purposes only. Accordingly, the spacing may vary as needed. The separation medium must have acceptable ultrasound transmission properties and may also serve to provide additional thermal insulation as well. For example, an epoxy may be used for the separation medium.

[00102] Figure 6L illustrates a variation of a device **680** of the present invention wherein the transducer assembly **670** comprises a tip **672**, an ultrasound coupling medium **674**, a transducer **676**, and an extension member **678**. In this variation of the invention, the tip **672** of the device serves as an acoustic lens and also has conductive areas (not shown) which serve as RF electrodes. As shown in Figure 6M, the tip **672** may extend from the device **680** and separate from the transducer **676**. Separation of the tip **672** protects the transducer **676** from heat or RF energy as

the tip **672** creates a channel in tissue. The extension member **678** may serve as a conductor to connect the tip **672** to an RF energy supply (not shown). When the tip **672** of the device **680** is being used in an ultrasound mode, the tip **672** may be coupled to the transducer **676** via the use of an ultrasound coupling medium **674**. Any standard type of ultrasound gel material may be used, also highly formable silicone may be used. It is desirable to use a fluid boundary layer (such as the gel) which may be permanent or temporary. In those cases where the boundary layer is temporary, subsequent applications of the boundary layer may be necessary.

[00103] Figure 6N illustrates another variation of a device **682** of the present invention having a tip **684** and transducer **686** that are separable from each other. Again, the tip **684** may include conductive areas and serve as both an RF electrode (not shown) as well as an acoustic lens. As shown in Figure 6N, the tip **684** may be separable from the transducer **686** when creating a channel to protect the transducer **686** from heat or RF energy. The tip **684** may be placed in contact with the transducer **686** for operation in an ultrasound mode, or the device **682** may contain a separation medium **688** which permits acoustic coupling of the transducer **686** with the tip **684** when separated.

[00104] Figures 6P-6U illustrate variations of RF electrode tip **690** configurations for use with the present invention. As illustrated, the electrodes may be placed around a circumference of a tip, longitudinal along a tip, spirally along a tip, or a combination thereof. The electrodes **692**, **694** may be used with a device having an acoustic lens or the electrodes may be employed solely as an RF hole-making device. While the variations illustrated in Figures 6P-6U show bipolar RF devices, the invention may also use a single electrode (monopolar.) The tip **690** may contain a first electrode **692** separated from a second electrode **694** by an electrical insulator **696** (e.g., ceramic, or plastic insulator). In variations of the device where electrodes are positioned on an acoustic lens, a sufficient amount of surface area of

the lens must remain uncovered so that sufficient coupling remains for transmission of a signal between the lens and tissue. Figure 6V illustrates a co-axial variation of a bi-polar RF tip having a first electrode **692**, a second electrode **694**, and an insulator **696**.

[00105] Figure 6W and 6X illustrates additional variations of the lens of the present invention. Figure 6W illustrates a device **724** with an acoustic lens **726** having an oblate spheroid shape. Figure 6X illustrates a device **728** with an acoustic lens **730** having a prolate spheroid shape. Figure 6Y illustrates a device **732** having a conical-shaped acoustic lens **734**. These variations are only intended to illustrate variations of the lens. It is contemplated that the shape of a lens may not follow a mathematical description such as conical, prolate, oblate or hemispherical. The design of the shape relates to the distribution pattern of the signal over the lens. The shapes can affect the distribution pattern by making it wider or narrower as needed. In any case, the lens is of a shape that provides coverage over the front face of the device.

[00106] Figure 7A illustrates a variation of the invention where a device **700** includes a heat-sink member **702**. The heat-sink member **702** may preserve surround tissue during creation of the collateral channel. Or, the heat-sink member **702** may be a section of conductive material or a balloon. The heat-sink member **702** may be in fluid communication with a lumen **704** that provides a fluid, such as saline, that conducts heat away from the area surrounding the channel.

[00107] Figure 7B illustrates another variation of a device **710** having a fluid delivery assembly **706** which assists in preserving surrounding tissue while a channel is being created. The fluid delivery assembly **706** may spray, mist, or otherwise apply fluid **708** to the area surrounding the channel. For example, cooled saline may be applied to the area to prevent excessive heating of the target area.

[00108] The invention includes the use of hole-making assembly on the side of the device with a transducer assembly on the tip of the device. For example, Figure 7C illustrates a variation of an RF electrode **712** for use with the present invention. The electrode **712** may be a protrusion extending from a conductive member **716** that is covered with an insulating material **714**. In this variation, the electrode **716** limits the depth of the channel due to the amount of material extending from the conductive member **716**. The conductive member **716** may be connected to a source of RF energy (not shown) or may use another heating element (not shown). Figure 7D illustrates another variation of an electrode configuration. In this variation, the electrode comprises a spherical member **718** extending from an elongate member **722**. The electrode **718** is retractable through the elongate member **722** by use of an actuator **720**. The actuator **720** may be conductive and connected to a source of RF energy to conduct energy through the electrode **718**. Again, the design of the electrode **718** limits the depth of penetration of the electrode **718** while creating a channel in tissue. The electrodes described herein may also be used in conjunction with a device having a Doppler arrangement.

[00109] Also, a variation of the invention contemplates the delivery of drugs or medicines to the area of the collateral opening. Also contemplated is the use of a fibrin, cyano-acrylate, or any other bio-compatible adhesive to maintain the patency of the opening. For example, the adhesive could be deposited within the collateral channel to maintain patency of the channel or to create a cast implant of the channel. The adhesive could also coat the channel, or glue a flap to the wall of the airway. Also, the use of a bioabsorbable material may promote the growth of epithelium on the walls of the conduit. For example, covering the walls of a channel with small intestine submucosa, or other bioabsorbable material, may promote epithelium growth with the bioabsorbable material eventually being absorbed into the body.

[00110] Figure 4 illustrates a variation of a device **400** having the ability to create multiple openings within the walls of the natural airway **100**. The holes may be created by dilation, cutting, electrical energy, microwave energy, ultrasonic energy, laser, chemical, or any process as mentioned above. This device **400** may also be used to deploy multiple probes to determine the location of a blood vessel (not shown) using one of the procedures mentioned above.

[00111] Figure 5A illustrates an implant or conduit **500** placed within a natural airway **100**. As shown, the airway **100** has a portion of its wall removed, thereby providing a collateral opening **112** within the airway **100**. The implant **500** typically has a porous structure which allows gasses to pass between the airway and the channels **112** and into the lung. Moreover, the structure of the insert **500** also maintains patency of the airway **100** and the channel **112**.

[00112] Any variation of a conduit described herein may comprise a barrier layer which is impermeable to tissue. This aspect of the invention prevents tissue in-growth from occluding the channel. The barrier layer may extend between the ends of the body or the barrier layer may extend over a single portion or discrete portions of the body of the conduit.

[00113] Figure 5B illustrates an conduit **500** having an expandable structure within an airway **100**. Usually, the conduit **500** has a porous wall that allows the passage of gasses through the wall. The conduit **500** is delivered via a delivery device **502** which may also contain an expandable member (not shown) which expands the conduit **500**. As shown in figure 5C, the conduit may have piercing members **504** attached on an outer surface which enable the conduit **500** to create an incision within the airway **100**.

[00114] Figure 5C illustrates the conduit **500** after being expanded by an expandable member **506**, e.g. a balloon device, an expandable mechanical basket, or an expandable wedge. In this example, the conduit **500** expands through the walls of

the airway **100** at sections **508**. In this variation, the conduit **500** is lodged within the walls of the airway **100**.

[00115] Figure 5D illustrates a grommet-like insert **503** where the lumen of the insert **503** extends longitudinally through the collateral channel. In this example, an expanding member **501**, e.g., a balloon, an expanding mechanical basket, or the like is used to secure the conduit **503** within the collateral channel.

[00116] Although not illustrated, the invention includes conduits having a length to diameter ratio approximately 1:1. However, this ratio may be varied as required. The cross-section of an implant may be circular, oval, rectangular, elliptical, or any other multi-faceted or curved shape as required. The cross-sectional area of an implant **500** may be between 0.196 mm² to 254 mm².

[00117] The conduit may also be any device capable of maintaining a patent opening, e.g., a plug, that is temporarily used as a conduit and then removed after the channel has healed in an open position. In another variation the plug may be a solid plug without an opening that is either bio-absorbable or removable. In such a case, the plug may be placed within an opening in tissue and allow the tissue to heal forming a collateral channel with the plug being ultimately absorbed into the body or removed from the body.

[00118] Another variation of the conduit is illustrated in figure 5E. In this example the conduit **510** comprises a cone **514** with a grommet **512** for attachment to a wall of the airway **100**. The cone **514** may be porous or have other openings **516** to facilitate the passage of gas through the collateral channel. In the event that the distal opening of the cone become occluded, the porous cone permits the continued exchange of gasses between the collateral channel and the natural airway.

[00119] Another variation of the conduit is illustrated in figure 5F. For example, the conduit **518** may be configured in a 't-shape' with a portion **520** of the conduit extending through the collateral channel. Again, the conduit **518** may be

constructed to have a porous wall to allow gas exchange through the wall. The conduit may be configured in a variety of shapes so long as a portion of the conduit extends through the collateral channel. The portion may be formed into a particular shape, such as the 't-shape' described above, or, the portion may be hinged so that it may be deployed within the channel. In such a case, a portion of a wall of the conduit may have a hinge allowing the wall of the conduit to swivel into a channel.

[00120] Yet another variation of the conduit is found in figure 5G. In this example, the conduit **522** is constructed with a geometry that reduces the chance that the conduit **522** will migrate within the airway **100**.

[00121] Figure 5H illustrates an example of a conduit **524** having an asymmetrical profile. The conduit **524** may have a flange **526** at either or both ends of the body **528**. Although not shown, the flange **526** may have a cone-like profile to facilitate placement within an airway. As illustrated in figure 5J, the asymmetrical profile of the conduit **524** assists in preventing obstruction of the airway.

[00122] Figure 5K illustrate a variation of the conduit **530** having a self-cleaning mechanism. In this example, the self cleaning mechanism is a floating ball bearing **532**. The ends of the conduit **530** have a reduced diameter **534** which prevents the bearing **532** from escaping. As gas passes through the conduit **530**, the bearing **532** moves about the conduit **530** clearing it of debris. The shape of the bearing **532** and the size and shape of the reduced diameter **534** may be varied to optimize the self-cleaning effect of the device.

[00123] Figure 5L and 5M illustrate another variations of a self-expanding conduit **536**. In this example, as shown in figure 5L, the conduit **536** may be constructed from a flat material **538** having a spring or springs **540**. As shown in figure 5M, the conduit **536** is formed by rolling the assembly. The spring **540** provides an expanding force against the material **538**. The conduit **536** may also be

constructed so that the flat material **538** is resilient thus eliminating the need for springs **540**.

[00124] Figure 5N illustrates another variation of an expandable conduit **542** constructed from a braided material. The conduit **542** may be constructed so that the diameter is dependent upon the length of the device **542**. For example, the diameter of the device **542** may decrease as the length is stretched, and the diameter may increase as the length of the device **542** is compressed. Such a construction being similar to a 'finger cuff' toy.

[00125] Figures 5O-5Q illustrate another variation of a grommet-type conduit. Figure 5O illustrates a conduit **544** having expandable ends **546**. In one variation the ends **546** of the device **544** may flare outwards as illustrated in figure 5P. Figure 5O illustrates another variation of the device **544** in which the ends **546** compress in length to expand in diameter.

[00126] Figures 5R and 5S illustrate variations of a conduit having an anchor. In figure 5R, the conduit **548** has an anchor **550** at a distal end of a hollow plug **540**. The anchor **550** may be tapered to facilitate entry into the airway **100** wall or may have another design as required. The anchor **550** also contains ventilation openings **552** to facilitate gas exchange through the device. Figure 5S illustrates another variation of the device.

[00127] Figure 5T illustrates a variation of a conduit **561** having flanges **563** at either end to assist in placement of the conduit within an airway wall (not shown). The ends of the conduit **565** may be tapered to ease placement through a collateral channel. The conduit has an opening **565** to facilitate passage of air. To simplify construction, the conduit **561** may be constructed from a biocompatible material, such as stainless steel, or plastic.

[00128] Figure 5U illustrates a variation of the invention having multiple openings for gas flow. The conduit **560** has a first hollow end **564** which can extend

through a wall of the airway **100** and a second hollow end **566** which can remain parallel to the airway **100**. This example also includes an opening **562** which allows gas to flow through the airway **100**.

[00129] Figure 5V illustrates a variation of the device having a one-way valve **570**. The valve **570** allows the conduit **568** to permit exhaust of the air sac but prevents the conduit **568** from serving as another entrance of gas to the air-sac. The valve **570** may be placed at ends of the conduit or within a lumen of the conduit. The valve **570** may also be used as bacterial in-flow protection for the lungs.

[00130] Figure 5W illustrates another variation of a conduit **572**. In this variation, the conduit **572** may be a sponge material, or constructed of an open cell material **574**, which allows air flow through the material. Or, the conduit **572** may have lumens **576** which allow flow through the conduit **572**. To assist the conduit **572** in remaining within a channel, the conduit material may be selected such that it expands as it absorbs moisture. Also, the sponge material/open cell material may be bio-absorbable to allow for temporary placement of the conduit **572**.

[00131] Figures 8A-8F illustrate another variation of a conduit **800** of the present invention. The conduit **800** has a center section **802** having extension members **804** located at either end of the center section **802**. The center section **802** illustrated is tubular but may be of any other shape as needed for the particular application. The conduit of the invention has a passageway extending between the ends of the conduit suited for the passage of air. The variation of the conduit **800** illustrated in Figure 8A has a center section **802** comprising a mesh formed from a plurality of ribs **806**. Figure 8A and 8B illustrate the conduit **800** in a reduced profile while Figure 8C and 8D illustrate the conduit **800** in an expanded profile after expansion of the center section **802** of the conduit **800**. As shown in Figures 8E and 8F, each free end **808** of each extension member **804** is unattached to the center section **802** and is bendable about the respective end of the center section **802** to

which it is attached. Accordingly, once a conduit **800** is placed within a collateral channel (not shown), the extension members **804** are bent about the end of the center section **802** and form a cuff or grommet which assists in keeping the conduit **800** within a collateral channel. Accordingly, the cross section and number of extension members **804** located about either end of the conduit **800** may be selected as necessary to assist in placement and securing of the conduit **800** within a channel.

[00132] The conduits described herein may have a fluid-tight covering, as discussed below, about the center section, the extension members, or the entire conduit. Also, the conduit may be designed to limit a length of the center section to less than twice the square root of a cross sectional area of the center section when the center section is in the expanded profile.

[00133] Figure 8G-8I illustrates another variation of a conduit **812** for use with the invention. In this variation, the conduit **812** is formed from a rolled sheet of material **810**. The rolled sheet **810** may be heat treated to preserve the shape of the conduit **812** or the sheet **810** may simply be rolled to form the conduit **812**. In those cases where the sheet of material **810** comprises a shape-memory alloy, it is desirable to process the material **810** so that it exhibits super-elastic properties at or above body temperature.

[00134] Figure 8G illustrates a variation of extension members **820** for use with a conduit (not shown) of the present invention. In this variation, the extension members **820** have an attachment **822** between adjacent extension members **820**. Figure 8H illustrates the extension members **820** as the conduit (not shown) is expanded and the extension members **820** are bent on the conduit. The attachment **822** assists in preventing the extension members **820** from deviating from a preferred position. As illustrated in Figure 8I, the conduit **826** may have cut or weakened sections **824** to facilitate expansion of the conduit **826** and bending of the extension members in a desired manner (as shown by the section of **828**).

[00135] Figures 8J-8K illustrate various additional cross sectional designs of conduits. Figure 8J illustrates a possible conduit design **830** having extension members **834** attached to a center section **832**. Figures 8K and 8L illustrate additional variations of conduit designs. As illustrated in Figures 8K and 8L, the extension members **840, 846** and center sections **838, 844** are designed to form a diamond pattern upon expansion of the conduit. Figure 8K further illustrates a variation of an extension member **840** having an opening **841** to facilitate tissue in-growth and thereby secures placement of the conduit. Figure 8M illustrates an expanded conduit **848** having the diamond pattern referred to above. The conduit **848** also contains a fluid-tight barrier **851** on the center section **850** of the conduit **848**. Although not illustrated, fluid-tight barrier may be placed throughout a conduit. Another feature of the variation of Figure 8M is that the extension members have a diamond pattern construction, this construction assists in maintaining alignment of the extension members allowing for a preferred aligned expansion of the extension members.

[00136] Figures 8N-8O illustrate another variation of a conduit **860** of the present invention. In this variation, the conduit design **854** may have extension members **856** at only one end of the conduit **860**. In this variation, the center section of the conduit may comprise a body portion **858**. The conduit **860** may have a covering about a portion of the conduit **860**. The covering may extend throughout the length of the conduit **860** or it may be limited to a portion of the conduit **860**. As illustrated in Figure 8O, when expanded, the conduit **860** may form a reduced area **858** near the extension members **856**. As mentioned above, the conduit cross section **854** may be designed such that the a diamond pattern is formed upon expansion of the conduit **860**, as illustrated in Figure 8O.

[00137] Figure 8P illustrates a sheet of material **810** having extension members **814** extending from either end of the sheet **810**. Although the sheet **810** is illustrated

to be solid, a conduit may be formed from a sheet having openings within the center section of the sheet. Figure 8Q illustrates the conduit **812** where the rolled sheet **810** comprises a center section **818** of the conduit **812** and the extension members **814** from either end of the center section **818**. As illustrated in Figure 8Q, the sheet **810** may be overlapped for a reduced profile and expanded into an expanded profile. Figure 8R illustrates a free end **816** of each extension member **814** as having been bent away from a central axis of the conduit **812**. As with any variation of a conduit of the present invention, the extension members **814** of the conduit **812** may be bent away from a central axis of the conduit **812** up to 180° with respect to the central axis. As mentioned above, the cross section and number of extension members **814** located about either end of the conduit **810** may be selected as necessary to assist in placement and securing of the conduit **810** within a channel.

[00138] In those cases where the conduit **812** of figure 8Q comprises a non-shape memory alloy the conduit **812** will be actively mechanically expanded. In those cases where the conduit **812** is comprised of a shape memory alloy, such as a super-elastic alloy, the conduit **812** may be pre-formed to assume a deployed shape which includes a grommet formed by extension members **814** and an expanded center section **818**, such as the shape illustrated in Figure 8R. Next, the super-elastic conduit **812** may be restrained or even rolled into the shape illustrated in Figure 8Q. Because the conduit **812** is formed of a super-elastic material, no plastic deformation occurs. When the super-elastic conduit **812** is then placed within a collateral channel, the conduit **812** may naturally resume its pre-formed, deployed shape.

[00139] Figure 8S illustrates another variation of a conduit **862** having a first portion **864** and a second portion **866** and a passageway **868** extending therethrough. The first portion **864** may be a conduit design as described herein. In particular, the first portion **864** is configured to secure the conduit **862** to the airway wall **100**. Accordingly, the first portion **864** may or may not have a center that is expandable.

The walls of the first portion **864** may be fluid-tight (either through design, or a fluid tight covering) to prevent tissue in-growth through the collateral channel.

Alternatively, the first portion **864** may be partially fluid-tight to facilitate tissue in-growth to improve retention of the conduit **862** to the airway wall **100**. However, in the latter case, the first portion **864** should be designed to minimize tissue in-growth within the channel to prevent substantial interference with airflow through the conduit **864**. As with the first portion **864**, the walls of the second portion **866** of the conduit may or may not be fluid-tight. If the second portion **866** is not fluid-tight, the larger area provides for improved airflow from lung tissue through the passageway **868** and into the airway. The second portion **866** may also be designed to be partially fluid-tight to encourage airflow through the conduit **862** but reduce the probability of blockage of the conduit **862**.

[00140] Figures 8T-8U illustrate another variation of a conduit **870**. For example, the conduit **870** may be formed from a tube that is slit to form extension members at a first portion **872** and second portion **876** with a center section **874** between the portions. The conduit **870** may be expanded as shown in Figure 8U such that the first **872** and second **876** portions maintain the center portion **874** in a collateral channel in an airway wall. The center section **874** may or may not be expandable.

[00141] Figure 8U illustrates the second portion **876** of the conduit **870** to expand in its center, however, the conduit **870** may be designed in other configuration as well (e.g., expanded to have a larger diameter at an end opposite to the center section **874**.) However, a central aspect of this design is that the second portion **870** provides a large area in the lung tissue to permit a larger volume of air to pass from the lung tissue into the conduit **870**. This design has an added benefit as the second portion **876** cannot be easily blocked by flaps of parenchyma tissue. A simple variation of the conduit **870** may be constructed from a metal tube, such as 316

stainless steel, titanium, titanium alloy, nitinol, etc. Alternatively, the conduit may be formed from a rigid or elastomeric material.

[00142] The conduits described herein may be comprised of a metallic material (e.g., stainless steel), a shape memory alloy, a super-elastic alloy (e.g., a NiTi alloy), a shape memory polymer, a polymeric material or a combination thereof. The conduit may be designed such that its natural state is an expanded state and it is restrained into a reduced profile, or, the conduit may be expanded into its expanded state by a variety of devices (e.g., a balloon catheter.) The conduit described herein may be manufactured by a variety of manufacturing processes including but not limited to laser cutting, chemical etching, punching, stamping, etc.

[00143] The conduits described herein may be coated with an elastomer, e.g., silicone, polyurethane, etc. The coatings may be applied, for example, by either dip coating, molding, or liquid injection molding (for silicone). Or, the coating may be a tube of a material and the tube is placed either over and/or within the conduit. The coating(s) may then be bonded, crimp, heated, melted, or shrink fit. The coatings may also be placed on the conduit by either solvent swelling applications or by an extrusion process. Also, a coating may be applied by either wrapping a sheet of PTFE about and/or within the conduit, or by placing a tube about and/or within the conduit and securing the tubes.

[00144] As mentioned above, the number of and cross sectional area of the extension members on a conduit may be selected as needed for the particular application. Also, the extension members may be bent such that they anchor into the tissue thereby securing placement of the conduit. Or, the extension members or the center section may contain barbs or other similar configurations to better adhere to the tissue. Moreover, the orientation of the extension members may vary as well. For example, the extension members may be configured to be radially expanding from the center section, or they may be angled with respect to a central axis of the

conduit. Another variation of the invention includes a radioactive conduit which inhibits or prevents the growth of tissue within the conduit.

[00145] Although the conduits of the current invention have been described to contain expandable center sections, the invention is not necessarily limited as such. Instead, the design of the conduit may require extension members on the ends of a conduit with a non-expandable center section.

[00146] Figures 9A-9D illustrate a conduit **900** of the present invention. The deployment of the conduit **900** is intended to show an example of a possible means of deployment only. Accordingly, the inventive conduit may be delivered at an angle via an articulating or jointed device, the conduit may be delivered on a device that is adapted to locate and create the collateral channel, or the conduit may be delivered on a device having other features as needed for the particular application.

[00147] Figure 9A illustrates the conduit **900** being delivered to a collateral channel in an airway wall **114** via a delivery device (e.g., a balloon catheter **902**.) The conduit **900** may be attached to the delivery device **902** using the natural resiliency of the conduit **900**. Or, in those cases where the conduit is spring loaded, the conduit **900** restrained in a reduced profile and may be removably affixed to the delivery device **902** using an adhesive, or a removable sleeve such as a heat shrink tube. In this example, the balloon catheter **902** has several balloons including a distal balloon **904**, a proximal balloon **906**, and a center balloon (not illustrated in Figure 9A). Figure 9B illustrates the inflation of the distal **904** and proximal **906** balloons to situate the extension members **908**. Accordingly, the extension members **908** for a flange or collet about the airway wall **114**. The balloons **904**, **906** may be inflated simultaneously, or in a desired sequence. In any case, deployment of the balloons **904**, **906** may serve to center the conduit **900** in the collateral channel.

[00148] Figure 9C illustrates inflation of the center balloon **912** which causes expansion of the center section **910** of the conduit **900**. If the conduit **900** is affixed

to the delivery device **902**, expansion of the center balloon **912** causes release of the conduit **900** by release of the adhesive or breaking of the heat shrink tubing (not shown). In any case, the means of attachment may be bioabsorbable and remain in the body, or may remain affixed to the delivery device **902** and is removed with removal of the delivery device **902**. Figure 9D illustrates the conduit **900** affixed to the airway wall **114** after the delivery device **902** is removed from the site. Another method of deploying a conduit includes restraining the conduit about a delivery device using a wire or string tied in a slip-knot or a series of slip-knots. When the conduit is delivered to a desired location, the proximal end of the wire or string may be pulled which releases the wire/string and deploys the conduit. Figure 9E and 9F illustrate possible ways to manipulate a conduit **914** for placement in an airway wall **114** using a delivery device **916**. Figure 9E illustrates deployment of a delivery device **916** to place a conduit **914** within an opening in an airway wall **114**. The conduit **914** may be placed over a balloon **918** (or other expandable section) of the delivery device **916**. Figure 9F illustrates deployment of the balloon **918** to place and expand the conduit **914**. In the variation illustrated in Figures 9E and 9F, a balloon **918** serves several functions. The balloon **918** first expands and starts bending the extension members **920**. The balloon **918** continues to center the conduit **914** on the tissue and simultaneously begins to expand the conduit **914** and secures the conduit to the tissue.

[00149] Figures 9G and 9H illustrate additional variations of deployment devices. In these variations, the deployment devices **922**, **926** contain hourglass-shaped balloons **924**, **928**. The hour glass-shaped balloons **924**, **928** contain an interior profile **923**. For deployment of a conduit (not shown) of the present invention, the conduit is placed on the balloon **924**, **928**. As the balloon **924**, **928** expands, the conduit expansion matches the interior profile **923** of the balloon **924**, **928**. Accordingly, the hour glass-shaped balloon **924**, **928** may be used to set the

angle and orientation of the expandable members of a conduit as well as the expansion of a center section of the conduit.

[00150] Figure 9I illustrates another variation of an hour glass shaped balloon delivery device **930**. This variation of the hour glass shaped balloon **932** is designed to expand extension members (not shown) of a conduit (not shown) at a particular angle **934**. The orientation of the balloon **932** may be designed as needed to impart the desired angle to the extension members of the conduit. The balloons described herein may be constructed polyethylene terephthalate (PET) or any other material which is used in the construction of balloon catheters.

[00151] The invention further includes methods of evaluating individuals having a diseased lung to assess inclusion of the individual for the procedure.

[00152] The method comprises the steps of performing pulmonary function tests on the individual. The pulmonary function tests may obtain such values as FEV (forced expiratory volume), FVC (forced vital capacity), $FEF_{25\%-75\%}$ (forced expiratory flow rate), PEFR (peak expiratory flow rate), FRC (functional residual capacity), RV (residual volume), TLC (total lung capacity), and/or flow/volume loops.

[00153] FEV measures the volume of air exhaled over a pre-determined period of time by a forced expiration immediately after a full inspiration. FVC measures the total volume of air exhaled immediately after a full inspiration. $FEF_{25\%-75\%}$ measures the rate of air flow during a forced expiration divided by the time in seconds for the middle half of expired volume.. PEFR measures the maximum flow rate during a forced exhale starting from full inspiration. FRC is the volume of air remaining in the lungs after a full expiration. RV is the FRC minus the expiratory reserve volume. TLC is the total volume in the lungs at the end of a full inspiration. Flow/volume loops are graphical presentations of the percent of total volume expired (on the independent axis) versus the flow rate during a forced expiratory maneuver.

[00154] The invention further comprises methods to determine the completion of the procedure. This variation of the invention comprises the step of performing pulmonary function tests as described above, creating collateral channels in the lungs, performing a post-procedure pulmonary function test, obtaining clinical information, comparing the results of the tests, evaluating the clinical information with the results of the test to determine the effectiveness of the procedure.

[00155] Another method to determine the completion of the procedure includes checking the resistance of airflow upstream from a location of a collateral channel. The method includes making a collateral channel, checking airflow, measuring resistance to airflow, and repeating the procedure until acceptable resistance is obtained. Because the collateral channel allows for the release of trapped air, the resistance to airflow should decrease. A body plethysmograph or other suitable equipment used to measure in pulmonary medicine may be used to determine the resistance to airflow.

[00156] A measurement of total lung volume may be used to determine when the lung is suitably deflated and therefore when enough collateral channels are created. Or, non-invasive imaging may be used to determine pre and post procedure lung volume or diaphragm position.

[00157] An evaluation of the effectiveness of the procedure may also include creating a collateral channel then sealing the channel with a balloon catheter. The distal end of catheter is then opened for a measurement of the flow of trapped air through the catheter.

[00158] This variation of the invention includes obtaining clinical information regarding the quality of life of the individual before and after any procedures, physical testing of the pulmonary system of the individual, and a general screening for pulmonary condition.

[00159] The invention herein is described by examples and a desired way of practicing the invention is described. However, the invention as claimed herein is not limited to that specific description in any manner. Equivalence to the description as hereinafter claimed is considered to be within the scope of protection of this patent.